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10/712,228

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Maria da Graca Henriques Vicente

0210.1 Vicente

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03/20/2008

PATENT DEPARTMENT

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EXAMINER

CHONG, YONG SOO

ART UNIT

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1617

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/712,228 | Applicant(s) VICENTE ET AL. | |
| | Examiner YONG S. CHONG | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-13 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) 6,10,11,13,17,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7-9,12,15,16,18-20 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 1/10/2008. Claim(s) 2-3, 14 have been cancelled. Claim(s) 1, 4-13, 15-23 are pending. Claim(s) 1, 8-9, 13, 19-20 have been amended. Claim(s) 6, 10-11, 13, 17, 21-22 have been withdrawn. Claim(s) 1, 4-5, 7-9, 12, 15-16, 18-20, 23 are examined herein.

Newly amended claim 13 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. Applicant has previously elected Group I in the Restriction Requirement filed on 3/30/2007, which is drawn to a method of preventing or inhibiting infection by HIV by administering a porphyrin macrocycle of formula I. Claim 13, drawn to a method for killing HIV in or on a nonliving material by administering a porphyrin macrocycle of formula I, has been withdrawn as it does not read on the elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's amendments have rendered all 112, first paragraph rejections, in addition to the 112, second paragraph rejection, over claims 9-12, 20-23, moot, therefore hereby withdrawn. For clarification purposes, the above 112, second paragraph rejection, was mistyped with dashes instead of commas. The correct listing of claims should have been 9, 12, 20, and 23, which is obvious considering that claims

10-11 and 21-22 have been previously withdrawn. Nonetheless, this is moot since the rejection has been withdrawn as well.

Applicant's arguments have been fully considered but found not persuasive. The 112, second paragraph rejection over claims 8 and 19, as well as the 103(a) rejection of the last Office Action are maintained for reasons of record and modified below as a result of Applicant's amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "light having a wavelength, intensity, and duration sufficient to significantly enhance the compound's treatment of viral infection or killing of viruses" renders the claim indefinite as to what type, wavelength, intensity, and duration of light are sufficient to significantly enhance the compound's treatment of viral infection or killing of viruses. The specification does not define light that is sufficient to significantly enhance the compound's treatment of viral infection or killing of viruses. Therefore, the metes and bounds of patent protection sought for the instant claims have not been defined.

Response to Arguments

Applicant argues that a person of ordinary skill in the art would readily understand the concepts of exposing tissue to light, finding suitable wavelength, intensity, and duration of light that will enhance treatment. Such testing can only be considered routine. This is not persuasive because one of ordinary skill in the art would not know how to find suitable parameters of light to enhance the treatment of HIV infection in a human. Examiner views this as not routine experimentation in the field, therefore there would be undue experimentation to determine these suitable parameters in the context of treatment of HIV infection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-5, 7-9, 12, 15-16, 18-20, 23 are rejected under 35 U.S.C. 103(a) as being obvious over Debnath et al. ("Anti-HIV-1 activity of carborane derivatives of porphyrins," *Med. Chem. Res.*, vol. 9, pp. 267-273, 1999, of record) in view of Vicente et al. (WO 01/85736 A1, of record).

The instant claims are directed to a method of preventing or treating HIV infection by administering to a patient a porphyrin macrocycle comprising one or more carboranyl groups as depicted by compound 33 (Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt).

Debnath teach carborane derivatives of porphyrins, originally designed as boron neutron capture agents, also possess anti-HIV activity (title and abstract). Table 1 lists some examples of boronated porphyrins.

However, Debnath fail to specifically disclose compound 33.

Vicente teach carbon-carbon linked carboranyl-containing porphyrins as neutron capture agents for cancer therapy (title and abstract). A preferred compound is Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt (pg. 25). These porphyrins are used in boron neutron capture therapy for cancer treatment, which includes irradiation by red light (claim 27-29).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used the boron neutron capture therapy on a HIV infected patient by administering compound 33.

A person of ordinary skill in the art would have been motivated to use boron neutron capture therapy on a HIV infected patient by administering compound 33

because: (1) both Debnath and Vicente disclose boron neutron capture therapy; (2) both Debnath and Vicente disclose carbon-carbon linked carboranyl-containing porphyrins as neutron capture agents; (3) of the functional art equivalence of the porphyrins disclosed by Debnath and compound 33 disclosed by Vicente; and (4) Debnath teach carborane derivatives of porphyrins possess anti-HIV activity.

Therefore, the skilled artisan would have had a reasonable expectation of success in treating HIV infection in a patient by administering Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt or compound 33.

Response to Arguments

Applicant argues that Debnath and Vicente address different problems and employs different classes of chemical compounds, therefore cannot be combined with each other. Specifically, Debnath discloses compounds, in which carboranyl groups are ester linked to a porphyrin macrocycle, as neutron capture agents for the treatment of HIV infection. It is submitted that these ester linkages are susceptible to hydrolysis. On the other hand, Vicente teach the same compounds albeit with carbon-carbon bonding of the carboranyl groups, as neutron capture agents for cancer therapy. When such compounds are used as neutron capture agents for cancer therapy, the advantages of resistance to hydrolysis are straightforward. Accordingly, there is nothing in the prior art that shows hydrolysis of the carbonyl groups enhances antiviral activity.

This is not persuasive because the motivation to have used the porphyrin macrocycle (compound 33) as taught by Vicente in the HIV treatment regimen taught by

Debnath is because of the functional equivalence between the porphyrin macrocycles. Both are well known to be neutron capture agents. The advantages or disadvantages of hydrolysis of the carboranyl groups is irrelevant because Applicant has not establish a basis for what effect it might have or not have on HIV treatment in humans. Furthermore, Applicant is reminded that the standard for obviousness is not absolute, but rather a reasonable expectation of success.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617